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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ORTHO BIOTECH PRODUCTS, L.P.,	
Plaintiff,	
- v. -	Civ. No.: _____
AMGEN INC.,	
Defendant.	

PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF MOTIONS FOR PRELIMINARY INJUNCTION AND EXPEDITED DISCOVERY

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Plaintiff Ortho Biotech Products, L.P. ("Ortho") submits this memorandum of law in support of its motions for a preliminary injunction and for expedited discovery.

PRELIMINARY STATEMENT

This antitrust action, brought under Sections 1 and 2 of the Sherman Act, seeks, *inter alia*, to enjoin an anti-competitive tying arrangement and pricing scheme implemented on October 1, 2005 by defendant Amgen Inc. ("Amgen") in the oncology clinic market. The scheme ties substantial purchases of Amgen's Red Blood Cell Growth Factor ("RBCGF") drugs to its dominant White Blood Cell Growth Factor ("WBCGF") drugs, and is designed to enable Amgen to extend its monopoly in WBCGF drugs into the market for RBCGF drugs. Both of these drugs are needed by oncology clinics to treat cancer patients. The results of Amgen's scheme will be less competition, and less physician and patient choice.

Ortho sells Procrit®. Amgen sells Aranesp®. Both are RBCGF drugs that compete head-to-head in a two-player U.S. market. Annual combined gross sales to oncology clinics of these two products are expected to exceed $2.8 billion in 2005.

Amgen also sells Neulasta® and Neupogen®, which are WBCGF drugs with a combined 98% market share of sales to oncology clinics. Amgen has a monopoly in the market for WBCGF drugs. WBCGF drugs are a separate and distinct product market. Ortho does not sell a WBCGF drug.

At present, Aranesp accounts for approximately 65% of RBCGF drug sales to oncology clinics (the "relevant product market"). Over the past 18 months, Procrit's share of the relevant product market has dropped precipitously as the result of Amgen imposing pricing penalties for its monopoly WBCGF drugs on oncology clinics that do not agree to purchase

substantial amounts of their requirements of RBCGF drugs from Amgen (Aranesp) – instead of from Ortho (Procrit).

On October 1, 2005, these penalties became even more coercive. Amgen has now amended its contracts with oncology clinics to require clinics to face even steeper pricing penalties on Amgen's monopoly WBCGF drugs. To gain access to Amgen's contract rebates on its monopoly WBCGF drugs, a clinic must buy up to 75% of its RBCGF needs from Amgen. If a clinic wants to receive pre-October 1st contract rebate levels, it must increase its share of Amgen's RBCGF drugs up to 90%. Amgen's pricing scheme has reached the point where, for a substantial percentage of its patients, an oncology clinic is put in an untenable position. A clinic will actually end up losing several hundred dollars per administration if the clinic does not purchase all or almost all of its requirements for RBCGF drugs from Amgen.

Defendant's conduct constitutes a *per se* unlawful tying agreement in violation of Section 1 of the Sherman Act. Amgen's pricing scheme leaves oncology clinics with no economic alternative but to meet Amgen's demands. Amgen unquestionably has market power with respect to sales of WBCGF drugs. WBCGF and RBCGF drugs are distinct and separate products and a not insubstantial amount of commerce is involved.

Amgen's conduct also constitutes an attempt to monopolize in violation of Section 2 of the Sherman Act. The purpose of Amgen's anticompetitive pricing scheme is to monopolize the oncology clinic market for RBCGF drugs in the United States in which Procrit is Amgen's only competitor. Unless enjoined, there is a dangerous probability that, by engaging in this exclusionary conduct, Amgen will succeed in its monopolistic plans.

The anticompetitive conduct at issue here will irreparably harm Ortho. If Amgen is not blocked from pursuing this new pricing scheme, Procrit's ability to compete in the oncology clinic market for RBCGF drugs largely will cease.

Since Procrit was introduced in 1991, it has been used to treat millions of patients suffering from debilitating anemia that chemotherapy often produces. Procrit was the first RBCGF drug on the market and has changed the lives of millions of patients. Ortho is viewed by thought leaders in the oncology market as the pioneer in addressing the needs of cancer patients undergoing chemotherapy. As a result, Ortho has longstanding relationships with clinics and enormous good will in the Procrit brand. An award of damages years from now will not compensate Ortho for the immeasurable loss of relationships, good will and presence in the market place that will result if Amgen is able to proceed with its scheme.

Finally, absent a preliminary injunction, many clinics and ultimately many patients will be denied access to Procrit. This is not in the public interest.

For these reasons and as described further below, the Court should grant Ortho expedited discovery, set this matter down for an evidentiary hearing and, upon completion of that hearing, grant Ortho a preliminary injunction.

STATEMENT OF FACTS[1]

A. Ortho and Amgen Compete in the Sale of Red Blood Cell Growth Factor Drugs

Procrit

Anemia is most commonly seen in patients with (1) chronic kidney disease either pre-dialysis or while undergoing dialysis, (2) undergoing chemotherapy or (3) undergoing zidovudine treatment for HIV disease. Anemia is caused by the depletion of the human hormone

[1] The facts supporting Ortho's motions are set forth in the accompanying declarations of Michael Yang ("Yang Decl.) and William F. Cavanaugh, Jr. ("Cavanaugh Decl.")

erythropoietin. Many patients suffering from severe anemia cannot lead normal, productive lives. Epoetin alfa is a synthetic form of erythropoietin that stimulates the production of red blood cells and is often referred to as a RBCGF drug. Prior to the introduction of epoetin alfa drugs, the treatment for severe cases of anemia was whole blood, or red blood cell blood transfusions. *See* Yang Decl. ¶¶ 2-3.

In 1985, Amgen granted Ortho an exclusive license under Amgen's patents to market and sell epoetin alfa in the United States for anemia in humans resulting from all treatments except one – anemia in patients undergoing dialysis for end stage renal disease ("ESRD"). Under the PLA, Amgen retained the right to market an epoetin alfa product for humans in this one field. *See id* at ¶ 4.

While the use of epoetin alfa to combat dialysis-induced anemia was already established at the time of the PLA, its use to treat anemia resulting from other disease states or treatments was unknown. Through costly research and clinical trials, Ortho demonstrated the efficacy of epoetin alfa to treat and reduce the need for transfusions in patients undergoing treatment for other diseases. Based upon this work, Ortho secured FDA approvals, beginning in 1991, to market Procrit for the treatment of persons who develop anemia as a consequence of (1) chemotherapy for cancer[2], (2) treatment of HIV infection with the pharmaceutical zidovudine, (3) chronic kidney diseases in pre-dialysis patients, and (4) in anemic patients scheduled to undergo elective, noncardiac, nonvascular surgery. *See* id at ¶ 5.

In 1991, Ortho launched Procrit, a branded version of epoetin alfa. Since then, it has been prescribed to millions who suffer from anemia included in the four indications listed above and became the standard of care for the treatment of chemo-induced anemia. As a result

[2] This is also known as "chemo-induced anemia."

of Procrit's success, Ortho has paid Amgen over $1.5 billion in royalties on Procrit sales. *See id* at ¶ 6.

Aranesp

In 1989, Amgen introduced Epogen®, its branded epoetin alfa, to combat anemia associated with dialysis for ESRD. However, pursuant to the PLA, sales of Epogen were limited to anemia associated with dialysis. Amgen was interested in circumventing the market exclusivity it had granted to Ortho to sell epoetin alfa for all purposes other than dialysis. *See id* at ¶¶ 4,7. The result was Amgen's introduction of Aranesp, a synthetic form of erythropoietin known as darbepoetin alfa. It was formulated by modifying the epoetin alfa molecule, thereby circumventing the exclusive rights granted to Ortho on epoetin alfa. In 2002, Amgen received regulatory approval to sell Aranesp, a branded RBCGF drug, to treat chemo-induced anemia. *See id* at ¶ 7.

Ortho and Amgen are the only two competitors for the sale of RBCGF drugs to treat chemo-induced anemia in the United States. Given the scope of Amgen's patents, barriers to entry into this market are extremely high. *See id* at ¶ 9.

B. Amgen Has a Monopoly on the Sale of White Blood Cell Growth Factor Drugs

Many cancer patients undergoing chemotherapy may, for different reasons, require a white blood cell growth factor ("WBCGF") drug to combat neutropenia, a white blood cell deficiency that is potentially life-threatening. Neutropenia is a side effect of chemotherapy which potentially compromises a patient's immune system. The disease occurs not only in some patients undergoing chemotherapy, but in individuals suffering from a number of diseases. *See id* at ¶ 10.

Amgen sells two WBCGF drugs, Neupogen® and Neulasta®. Neupogen was Amgen's initial WBCGF drug. In 2002, Amgen introduced Neulasta, a WBCGF product which has been modified so that one injection of Neulasta is roughly equal to 7 injections of Neupogen. The only other WBCGF drug is Leukine®, which is distributed by Berlex Laboratories. *See id* at ¶¶ 11-12. Ortho does not sell a WBCGF drug.

Amgen dominates the sales of WBCGF drugs, which have become the recognized standard of care for the treatment of neutropenia. Amgen has a 98% share of the sales to oncology clinics (with Neulasta alone having an 86% market share). Although Berlex's Leukine product has been on the market for many years, it has only a *de minimus* share of WBCGF sales. Unlike Amgen's WBCGF drugs which are administered by subcutaneous injection, Leukine must be administered intravenously -- a longer and more costly process. There are no potential entrants to the WBCGF drug market in the foreseeable future. *See id* at ¶¶ 11,13-14.

C. Amgen Seeks to Monopolize the Sales of RBCGF Drugs to Oncology Clinics by Leveraging its WBCGF Drug Monopoly

1. Sales of RBCGF Drugs to Oncology Clinics Constitute a Relevant Product Market

RBCGF drugs are sold through various channels. The roughly 2,400 oncology clinics in the United States represent the largest market for Procrit and Aranesp with over $2.8 billion in gross sales projected this year. "Oncology clinics" includes the small number of "mixed use" clinics that provide oncology as well as other clinic services. *See id* at ¶ 15.

To be successful, a seller of RBCGF drugs must have a strong presence in oncology clinics. These clinics, which are owned and operated by oncologists in private practice, are the preferred venue for patients to receive out-patient administration of RBCGF

drugs as well as WBCGF drugs. At present, the vast majority of outpatient administration of RBCGF drugs occurs in oncology clinics. *See id* at ¶ 16.

Both Amgen and Ortho have historically treated oncology clinics as a distinct market. A comparison of prices for Procrit shows that oncology clinics on average pay roughly 5% more for the drug than do hospitals, and Amgen in the past has offered substantial "off-invoice" discounts to hospitals, not available to oncology clinics.[3] *See id* at ¶¶ 17-19.

Government health care programs, such as Medicare, also treat oncology clinics differently than other purchasers. The amount of reimbursement and the formula utilized by the government are different than what are used for other industry participants, such as hospitals. *See id* at ¶ 21.

Most oncology clinics purchase drugs through entities called "specialty distributors." Specialty distributors deliver oncology drugs, which often require careful handling (e.g., refrigeration) to thousands of oncology clinics. These specialty distributors are licensed to distribute to oncology clinics. Oncology clinics have formed their own Group Purchasing Organizations ("GPO") to negotiate with drug manufacturers. *See id* at ¶¶ 22-23.

2. Amgen Begins Bundle Pricing on Aranesp and its WBCGF Drug Monopoly

Virtually all oncology clinics administer both RBCGF and WBCGF drugs to patients. Given this fact and Amgen's monopoly on WBCGF drugs, these clinics must buy WBCGF drugs, particularly Neulasta, from Amgen. *See id* at ¶ 27.

This fact was not lost on Amgen as it developed a marketing plan for Aranesp. Almost from the outset, Amgen's strategy for selling Aranesp has been to utilize its monopoly to

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[3] Hospitals cannot buy more RBCGF drugs than they need to arbitrage a portion of their purchases by reselling to oncology clinics. It has been a longstanding practice in the pharmaceutical business to have "own use" clauses in sales contracts precluding resale for profit. *See* Yang Decl. at ¶20.

penalize a clinic on the pricing of those WBCGF drugs if the clinic did not purchase substantial amounts of Aranesp, a product that has competition. The volume requirements in Amgen's pricing schemes for its RBCGF and WBCGF drugs are, in fact, disguised market share requirements designed to reduce Procrit's share of clinic sales by means other than competition on the price of RBCGF drugs on their relative merits. *See id* at ¶ 28.

The Early 2004 Contract

Amgen's penalties became even more coercive in the spring of 2004. At that time, Amgen began offering substantial "rebates" to oncology clinics on the condition that these facilities reach combined volume requirements for Amgen's RBCGF and WBCGF drugs. Amgen refers to these offerings on its RBCGF and WBCGF drugs as the Amgen Portfolio Contract ("APC"). *See id* at ¶ 29.

Amgen's pricing to oncology clinics under its APCs is broken into three groups – large, medium-sized and small accounts – based on the amount of RBCGF and WBCGF drugs purchased. Each account is given dollar volume usage targets that once reached allows the clinic to earn a specified level of rebate. The dollar volume targets Amgen puts in each clinic's APC represent a specific percentage requirement of market share based on a clinic's historical usage. Rebates are earned when Amgen's share of the clinic's estimated total APC purchases reach those levels. *See id* at ¶ 30.

For example, under the APCs in effect in the first half of 2004, a large account oncology clinic which purchased roughly 65% of its combined volume of RBCGF and WBCGF drugs from Amgen received a 13.5% rebate on its Aranesp purchases and a 10.5% rebate on its WBCGF drug purchases. However, an oncology clinic that purchased roughly 85% of its combined volume of RBCGF and WBCGF drugs from Amgen received significantly greater

rebates – a 25% rebate on its Aranesp purchases and a 25% rebate on its Amgen WBCGF drug purchases. An oncology clinic that did not meet its APCs volume requirements would only receive a minimal rebate. *See id* at ¶ 31.

The Late 2004 Amgen Contract

Later in 2004, Amgen modified its APCs. Amgen apparently recognized that simply providing oncology clinic with a combined dollar volume target might give the clinic the flexibility of loading up on Amgen's WBCGF drugs to meet its combined dollar volume target. As a result, Amgen imposed restrictions on the amount of WBCGF drugs that may be considered for purposes of reaching the specified dollar volume targets or higher rebate levels. This forced oncology clinics to purchase more Aranesp which was not subject to any incentive restrictions to reach higher rebate levels. *See id* at ¶ 32.

Amgen also required minimum dollar volume requirements for Aranesp. In addition, Amgen increased the rebates offered to oncology clinics, further penalizing those oncology clinics that failed to meet the dollar volume requirements set forth in each clinic's APC. With these changes to the APC, Amgen sought to more closely tie the rebates on its monopoly WBCGF drugs to the purchase of substantial amounts of Aranesp. *See id* at ¶¶ 32-33.

Under the modification to the APCs in late 2004, a large oncology clinic that purchased roughly 65% of its combined volume of RBCGF and WBCGF drugs from Amgen would receive an 18.5% rebate on its Aranesp purchases and a 10.5% rebate on its WBCGF drug purchases. However, an oncology clinic that purchased roughly 85% of its combined volume of RBCGF and WBCGF drugs from Amgen would receive a 30.0% rebate on its Aranesp purchases and a 25.0% rebate on its WBCGF drug purchases. All of these changes forced a clinic to buy

less Procrit and more Aranesp in order for the clinic to get access to both the WBCGF and RBCGF rebates. *See id* at ¶¶ 34-35.

As a result of these pricing schemes, Ortho's share of sales to oncology clinics has dropped precipitously. In the first quarter of 2004, Ortho had a 55% share of the oncology clinic market for RBCGF drugs and Amgen had a 45% share. At present, Ortho's share is estimated to be approximately 34%, with Aranesp having a 66% share. This significant shift in relative market share is attributable to oncology clinics being coerced by Amgen to replace substantial volumes of Procrit with Aranesp in order for these customers to gain access to acceptable pricing on the WBCGF drugs they must buy from Amgen. *See id* at ¶¶ 36-37.

The effect of Amgen's coercive tying arrangements on sales of RBCGF drugs to oncology clinics is evidenced by comparing Procrit and Aranesp market shares to oncology clinics with their respective share of sales in another market – sales to retail drug stores – where Amgen has not introduced these tying arrangements. As a result, Procrit and Aranesp compete head to head without interference from Amgen's WBCGF monopoly drugs. Procrit's share of sales to retail drug stores remains at approximately 70%. *See id* at ¶38.

3. Amgen's New Pricing Scheme is Designed to Eliminate Procrit from the Oncology Clinic Market.

Having gained a 65% share of sales to oncology clinics by tying access to WBCGF drug rebates to substantial purchases of Aranesp instead of Procrit, Amgen has now sought to tighten its squeeze on this market. Effective October 1, 2005, Amgen's pricing scheme became significantly more coercive.

As with the old pricing scheme, each clinic is given a series of levels of dollar volume targets for its total Amgen purchases of RBCGF and WBCGF drugs, as illustrated below

for a large account The higher the Amgen gross purchases the higher level of rebate an oncology clinic can achieve:[4]

	Rebates		
	Aranesp	Neulasta®	Neupogen
Level of Amgen Purchases			
6	26.0%	21.0%	20.0%
5	25.5%	20.5%	19.0%
4	25.0%	20.0%	18.0%
3	24.5%	19.5%	17.0%
2	24.0%	19.0%	16.0%
1	23.5%	18.5%	15.0%
base level	23.0%	18.0%	14.0%

However, to gain access to even the lowest rebate level described above an oncology clinic must now meet separate Aranesp and Neulasta dollar volume triggers. To avoid being penalized on its purchases of Amgen's dominant WBCGF drugs, the dollar volume for Aranesp purchases that an oncology clinic must achieve is now based on up to 75% of the oncology clinic's total RBCGF product purchases being Aranesp, i.e., a 75% market share. *See id* at ¶ 41.

A higher initial dollar volume threshold for Aranesp is only the start of this latest tying scheme. The true purpose of the new pricing scheme is to require oncology clinics to make Aranesp more than 75% of their RBCGF purchases. Under the modified APCs, for an oncology clinic to receive the same aggregate value it had been receiving while performing under the pre-October 1st APC (described above), each clinic now must reach higher dollar volume (i.e., market share) levels of Aranesp. For example, for a large clinic, the top Aranesp rebate is now 26%. This is 4% less than under the previous Amgen bundle of 30%. However, the clinic can

[4] *See id* at ¶¶ 39-40

earn back the additional 4% by taking its Aranesp share up to 90% as well as ensuring that Neulasta represents 90% of its WBCGF drug purchases. Thus, this new pricing scheme is intended to raise the Aranesp levels well above the initial threshold number needed to qualify for any rebate. *See id* at ¶ 42.

The new pricing scheme also reduces the highest Neulasta rebate from 25% to 21% for large clinics. As with the Aranesp rebates, an oncology clinic can earn back the 4% on Neulasta if 90% of its WBCGF drug purchases are of Amgen's Neulasta and the higher threshold for Amgen's Aranesp (up to 90%) is met. *See id* at ¶ 43.

The October 2005 addendum to the APC continues to place limits on the amount of the WBCGF drugs that may be considered for purposes of determining rebate levels on gross purchases. Conversely, the APC does not place caps on Aranesp. This further drives oncology clinics to purchase all or substantially all of their RBCGF drugs from Amgen. *See id* at ¶ 44.

A clinic that does not meet its Aranesp volume requirement will only receive a 4% rebate on Neulasta. Previously, an oncology clinic that did not meet its Aranesp dollar volume target requirements in its APC nonetheless would receive a rebate of 7.1% to 9.5% on Neulasta. Thus, a non-conforming oncology clinic is now being penalized an additional 3.1% to 5.5% on its Neulasta purchases. *See id* at ¶ 45.

4. <u>The Impact of this Pricing Scheme on an Oncology Clinic's Medicare Business.</u>

Failing to achieve a dollar volume of purchases of Aranesp roughly equivalent to a 75% market share will have severe economic consequences on an oncology clinic. Because the use of WBCGF drugs is the standard of care to treat neutropenia, oncology clinics have no choice but to carry Neulasta. *See id* at ¶ 46.

Medicare patients make up roughly 40% of the patient population treated in oncology clinics. As such, the economics of treating this patient group is a major consideration for any clinic. Without the Neulasta rebates (up to 25%), under the government's current reimbursement formula an oncology clinic would have to pay Amgen hundreds of dollars more on each treatment of Neulasta for a Medicare patient than the clinic will receive in reimbursement from the government and patients. *See id* at ¶ 47.

On January 1, 2005, the federal government changed the formula by which doctors and clinics are reimbursed for the drugs they purchase and administer in their offices. The new formula is based on the drugs' average selling price ("ASP" as it is known in the industry) plus 6%. Thus, if a clinic bought a drug that had an ASP of $1,000, the clinic would be reimbursed $1,060. This reimbursement amount is static regardless of what the particular clinic actually paid for the drug. The "plus 6%" is not intended to be profit to an oncology clinic. It is to provide the clinic with some cover on costs associated with the acquisition and storage of the drug, other costs associated with purchasing expensive drugs that require refrigeration, and bad debt from patients who do not make co-pays. *See id* at ¶ 48.

As the term suggests, the ASP of a drug is an average based on the prices paid – and discounts and rebates earned – by all purchasers of such drugs. Accordingly, a Medicare provider that does not, or can not, – avail itself of all of the rebates offered by a manufacturer can end up paying the manufacturer more for the drug than the drug's ASP and even more than the amount the provider will be reimbursed by the government (ASP + 6%). Where the price paid exceeds the reimbursement amount, the provider will actually realize a loss on the acquisition of a particular drug. *See id* at ¶ 49.

Unless an oncology clinic qualifies for Amgen's rebates, this is precisely the situation the clinic will face when it administers Neulasta, Amgen's dominant WBCGF product, as the following example illustrates: Neulasta's list price is $2,603.00. The Medicare reimbursement (i.e., ASP plus 6%) per unit of Neulasta currently is $2,078.066 in 4th quarter 2005 as published by the Centers for Medicare and Medicaid Services ("CMS"). That amount is 20.17% or $524.93 below Neulasta's list price due to the rebates and incentives previously granted by Amgen. Thus, to break even on a per treatment basis, a clinic must receive rebates and discounts equal to 20.17% below Amgen's list price. Amgen currently provides oncology clinics with just a 5% discount off list price and a 4% rebate if the clinics fail to buy the requisite levels of Aranesp specified in their modified APCs. In other words, unless the clinics meet the Aranesp volume requirements, the clinic will pay Amgen $295.87 more per administration of Neulasta than the clinic is being reimbursed by the government. *See id* at ¶ 50.

The foregoing example is based on Neulasta's existing list price. Amgen is in the process of increasing the list price of Neulasta. A list price increase will result in an oncology clinic losing even more money. *See id* at ¶ 51.

Amgen's latest pricing scheme will force oncology clinics to attempt to meet Amgen's enhanced dollar volume requirements for Aranesp that translate into substantial market share requirements. This will create a strong incentive on the part of the oncology clinic to stock only Aranesp, or to reduce dramatically the level of Procrit stocked. Few oncology clinics will be able to bear the cost and financial risk of also stocking Procrit given the level of Amgen's dollar volume requirements for Aranesp. An oncology clinic which wanted to use even a small amount of Procrit would need to stock both Procrit and Aranesp but would have to carefully

manage and monitor relative usage of Aranesp and Procrit, with severe financial consequences should it err in this process. Most are in no position to take such risks. *See id* at ¶ 52.

Amgen's current efforts to leverage its monopoly in the WBCGF drug market by penalizing oncology clinics that do not buy substantial amounts of Aranesp, coupled with the Medicare reimbursement regime preclude Ortho from competing over the long-term in the RBCGF oncology clinic market. One Amgen official already has boasted to a Procrit customer that they expect 75% of existing Procrit customers will agree to Amgen's latest pricing scheme. Amgen already has nearly 65% of RBCGF drug sales in the oncology clinic market. The large scale conversion of existing Procrit accounts will effectively eliminate physician and consumer choice, as Procrit is driven out of the oncology clinic market. *See id* at ¶53.

D. Ortho's Ability to Respond Competitively is Constrained by Amgen's Tying Arrangement.

Ortho is an equally efficient competitor, and Ortho supports price competition between rival companies as the hallmark of a free market. Ortho is prepared and willing to engage in fair, head-to-head, price competition between Procrit and Aranesp. But given the way in which government reimbursement works for a large percentage of a clinic's patients, Amgen's scheme of tying rebates on its monopoly drug to purchases of its RBCGF drug effectively precludes Ortho from responding with commensurate price cuts. That will only result in Ortho inevitably pricing below cost and in less competition. *See id* at ¶ 54.

The government's reimbursement formula for Medicare patients for Procrit and Aranesp is based on each product's ASP plus 6%. Absent Amgen's tying arrangements in which WBCGF rebates are tied to Aranesp purchases, price competition between Aranesp and Procrit (in the form of discounts or rebates) would result in Aranesp and Procrit each having a lower

ASP as the government recalculates product ASPs. Here, the rebates provided on Neulasta, while tied by Amgen to an oncology clinic buying a certain volume of Aranesp, are not, and will not be, considered as the Aranesp ASP is recalculated by the government. As a result, offering Neulasta rebates tied to Aranesp purchases allows Amgen to make it financially attractive to buy Aranesp, but in a way which avoids the corresponding effect of a lower Aranesp ASP (which, in turn, provides an oncology clinic with a smaller cushion, in dollar terms, on reimbursement for Aranesp, i.e., 6% of a lower ASP). *See id* at ¶ 55.

Put simply, by tying together rebates on WBCGF drugs with purchases of Aranesp, Amgen is forcing Ortho to absorb on its one product the "discounts" Amgen has spread over two products. The result of Ortho having to absorb discounts on its one product, Procrit, is that it will drive the Procrit ASP down and correspondingly the level of government reimbursement on Procrit. Because, however, the WBCGF rebates are a disguised way of discounting Aranesp, the Aranesp ASP will not go down correspondingly. The lack of parity in the lowering of the ASPs of Procrit and Aranesp – because of the Amgen tie – puts Ortho at an enormous disadvantage and effectively precludes price competition. *See id* at ¶ 56.

If Ortho offers a discount on Procrit commensurate with discounts offered by Amgen on its WBCGF and RBCGF drugs, a lower ASP for Procrit will be recalculated by the government at subsequent reporting intervals. (ASPs are recalculated each quarter based on pricing data from two quarters earlier.) Procrit will then have to offer an additional discount on the lower ASP because an ASP plus 6% reimbursement on a lower ASP provides the clinic with less money to cover its costs (i.e., 6% of a lower ASP). While Ortho would be required to make up the difference in dollars to oncology clinics under a lower Procrit ASP, Amgen will not on Aranesp. Amgen's rebates are tied in large measure to its WBCGF drugs. Consequently, the

Aranesp ASP will not drop to the same extent as Procrit's. The result of Procrit having a lower ASP than Aranesp will force Ortho to continue to chase Procrit's ASP down – each drop in the Procrit ASP will require an additional discount on the lower ASP to make up the dollar discount to oncology clinics to cover their costs. Meanwhile, the Aranesp ASP remains stable because Amgen's WBCGF rebates will not affect the Aranesp ASP, although they are tied to and driving Aranesp sales. The Procrit price spiral will result in Ortho pricing Procrit below cost in order to match the Amgen's rebates on its WBCGF and RBCGF drugs. *See id* at ¶57.

It is anticipated that on January 1, 2006, the government will move hospital reimbursement for Medicare outpatients to an ASP reimbursement system. Hospitals reportedly will be reimbursed at ASP plus 8%. The adoption of an ASP reimbursement system in hospitals will allow Amgen to introduce into hospitals the same pricing scheme it is now using to foreclose competition in the sale of RBCGF drugs to oncology clinics. Amgen will again simply leverage its monopoly in WBCGF drugs to provide, in effect, rebates on Aranesp without impacting the Aranesp ASP. *See id* at ¶ 58.

E. Procrit is a Highly Effective Drug

Procrit was the subject of extensive clinical trials demonstrating its effectiveness in the treatment of anemia and millions of Americans have been administered Procrit over the past 14 years. Recent studies and reports continue to underscore Procrit's efficacy. *See id* at ¶¶ 59-63.

F. Ortho and the Public will be irreparably harmed if Amgen is permitted to proceed with this pricing scheme

Foreclosing Ortho from the oncology clinic market will have a devastating impact on Ortho. Ortho will lose important longstanding customer relationships as well as the goodwill built up over the years during which Procrit has been used to treat millions of cancer patients

suffering from the severe anemia that often accompanies chemotherapy. Amgen's actions will likely result in reductions in investments in ongoing research and development in order to provide better forms of treatment. The resulting impact on innovation is not in the public's interest. *See id* at ¶ 65.

Eliminating Ortho as an effective competitor in the oncology clinic market will also result in less physician choice and consumer harm. As the preceding section shows, physicians and patients should not be effectively cut off access to the benefits of Procrit—which many physicians would prefer to Aranesp based on efficacy and price (based on stand-alone pricing)—by virtue of Amgen's use of its monopoly leverage in the sale of WBCGF drugs. In the absence of Amgen's use of its WBCGF drugs to drive Aranesp sales, Procrit would remain widely used in oncology clinics. Instead, it may be on the verge of marginalization in this market. *See id* at ¶ 66.

ARGUMENT

I. A PRELIMINARY INJUNCTION SHOULD BE GRANTED.

To prevail on its motion, Ortho must demonstrate that: (1) it has a reasonable probability of success on the merits; (2) it will be irreparably harmed by denying the injunction; (3) there will not be greater harm to the nonmoving party if the injunction is granted; and (4) granting the injunction is in the public interest. *Highmark, Inc. v. UPMC Health Plan, Inc.*, 276 F.3d 160, 170-71 (3d Cir. 2001); *ACLU v. Reno*, 217 F.3d 162, 172 (3d Cir. 2000); *see also In Re Arthur Treacher's Franchisee Litig.*, 689 F.2d 1137, 1143 (3d Cir. 1982) (noting that the first two factors are the most important, and that the second two are considered "when they are relevant"). Ortho's motion satisfies all of these elements.

A. Ortho Is Likely to Succeed on the Merits.

1. Ortho Is Likely to Succeed On Its *Per Se* Tying Claim.

A tie is an arrangement in which a seller conditions, as a matter of contract or economic necessity, the sale of one product (the tying product) on the purchase of another product (the "tied product"). *See Northern Pacific Ry. Co. v. United States*, 356 U.S. 1 (1958). When the seller has market power in the tying product, the Supreme Court described the harm caused by such arrangements (id. at 6):

> They deny competitors free access to the market for the tied product, not because the party imposing the tying requirements has a better product or a lower price but because of his power or leverage in another market. At the same time buyers are forced to forego their free choice between competing products. For these reasons 'tying agreements fare harshly under the laws forbidding restraints of trade.' *Times-Picayune Publishing Co. v. United States*, 345 U.S. 594, 606, 73 S. Ct. 872, 879, 97 L.Ed. 1277 [1953].

The Supreme Court has repeatedly held that when certain tying arrangements involving a substantial amount of commerce are employed by a party with market power as to the tying product they are so likely to be anticompetitive and so likely to lack any redeeming virtue that they are *per se* violations of Section 1 of the Sherman Act. *See Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 9 (1984) ("it is far too late in the history of our antitrust jurisprudence to question the proposition that certain tying arrangements pose an unacceptable risk of stifling competition and therefore are unreasonable 'per se.'").

Consistent with *Jefferson Parish*, the Third Circuit has defined the elements of a *per se* tying arrangement to be "(1) a defendant seller ties two distinct products; (2) the seller possesses market power in the tying product market and (3) a substantial amount of interstate commerce is affected," and when these elements are established "the defendant's tying practices are automatically illegal without further proof of anticompetitive effect." *Town Sound and Custom Tops, Inc. v. Chrysler Motors Corp.*, 959 F.2d 468, 477 (3d Cir. 1992). And, of course where, as here, a tying arrangement is illegal *per se*, the Supreme Court has repeatedly held that no showing of anticompetitive effects is necessary and no alleged business purpose can justify their use. *See supra* pp. 28-29.

All of the elements of a *per se* tying arrangement are present here. Amgen has tied two distinct products –its RBCGF drug (Aranesp) and WBCGF drugs (Neulasta and Neupogen), thereby forcing purchasers who prefer Procrit to purchase Aranesp. *See supra* pp. 10-17. Amgen possesses market power in regard to sales of the tying product – Amgen's WBCGF drugs which have roughly a 98% share of oncology clinic sales. Amgen's tying arrangement will affect a not insubstantial amount of commerce. *See supra* p. 6.

Simply put, the tying arrangement that Amgen is now imposing on oncology clinics goes to the heart of what Section 1 of the Sherman Act seeks to bar – "a monopolist in the tying product market [using] that leverage to garner sales in a second market, thereby foreclosing competitors and monopolizing the formerly competitive tied product market too." *Id.* at 475.

a. RBCGF and WBCGF Drugs are Distinct Products.

Whether products are distinct under a tying analysis "turns not on the functional relation between them, but rather on the character of the demand for the two items." *Jefferson Parish*, 466 U.S. at 19. As long as there is "sufficient consumer demand" so that it is efficient to sell the two relevant products separately, the distinct products element is satisfied. *Eastman Kodak Co. v. Image Tech. Serv., Inc.*, 504 U.S. 451, 462 (1992).

RBCGF and WBCGF drugs are sold on a stand-alone basis. For example, Ortho does not sell WBCGF drugs and Berlex, a supplier of Leukine, a WBCGF drug, does not sell RBCGF drugs. *See supra* pp. 5-6. This alone is dispositive on this element. *See Eastman Kodak*, 504 U.S. at 462 (distinct products element can be satisfied from evidence that relevant products had been sold separate and apart from each other).

Moreover, patient demand for RBCGF and WBCGF drugs is distinct because the drugs treat different medical conditions. Not all patients who are prescribed an RBCGF drug as a result of chemotherapy-induced anemia need a WBCGF drug. Similarly, not all patients who are prescribed a WBCGF drug to increase their white blood cell count need an RBCGF drug. *See supra* pp. 4-5.

b. Clinics are Being Economically Coerced to Purchase Aranesp.

There are two types of illegal tying arrangements. The first type is where the purchaser is contractually obligated to purchase the tied product together with the dominant tying product. The second type is where the only economically feasible option is to purchase the tying

and tied products together, despite the fact that the defendant supplier may offer the tying product on a stand-alone basis.

Courts have held when the purchaser has only one economically rational option – to purchase the tying and tied products together, an unlawful tying arrangement exists. *See American Mfrs. Mut. Ins. Co. v. American Broadcasting-Paramount Theatres, Inc.*, 388 F.2d 272 (2d Cir. 1967); *Virtual Maint., Inc v. Prime Computer, Inc.*, 957 F.2d 1318, 1323 (6th Cir. 1992) (holding that "a tying arrangement clearly exists here because the large price differential between [the untied and tied prices of the products at issue] induces all rational buyers [to purchase the tying and tied products together.]"); *In re Data Gen. Antitrust Litig.*, 490 F.Supp. 1089, 1111 (N.D. Ca. 1980) (finding tie-in where it was "less expensive to buy" tying and tied products together); Julian O. Von Kalinowski, *Antitrust Law and Trade Regulation*, § 22.02 (3) ("A tying arrangement may result . . .if the pricing of the individual products is so onerous that the buyer is coerced to accept both products in a discounted package.").[5]

The Third Circuit has recognized the principle that where the arrangement at issue leaves the purchaser with no rational economic choice the tie would be unlawful. *See Bogus v. American Speech & Hearing*, 582 F.2d 277, 287 (3d Cir. 1978) (in a contractual tying case, the Court noted "In the absence of proof of such an express condition . . . the existence of a tie-in may be deduced from evidence of coercion or leverage in the tied product market); *Bogosian v.*

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[5] In *United States v. Loews's, Inc.*, 371 U.S. 38, 43 (1962), the Supreme Court affirmed a lower court judgment approving a consent decree that precluded tying arrangements even when the tying and tied products were also offered separately. That decree prohibited the parties to that decree from:

> entering into any agreement to sell or license the right to exhibit any feature film over any television station in which the differential between the price or fee for such feature film when sold or licensed alone and the price of fee for the same film when sold or licensed with one or more other film[s] has the effect of conditioning the sale or license of such firm upon the sale or license of one or more other films.

Gulf Oil Corp., 561 F.2d 434, 452 (3d Cir. 1977) (contractual tie exists where contract clauses "have the practical economic effect of precluding sale of other than the lessor's gasoline").

As described on pp. 6-15, Amgen's new tying arrangement penalizes oncology clinics when they buy Amgen's dominant Neupogen and Neulasta products if they do not satisfy volume commitment between 65-75% of their RBCGF drug purchases will be of Aranesp (with greater incentives if they go above these numbers). Indeed, under Amgen's new arrangement, a clinic *actually will lose money* on Medicare patients if the clinic purchases Neulasta without meeting its Aranesp dollar volume requirement. *See supra* p. 13-14.

Accordingly, the only economically viable option for oncology clinics will be to purchase both Amgen's WBCGF and RBCGF drugs together—even though many physicians would prefer Procrit to Aranesp if Aranesp competed head-to-head with Procrit and WBCGF drug discounts were not conditioned on purchasing Aranesp. *See supra* pp. 17-18. This is precisely the type of economic "forcing" that is the essence of an unlawful tying arrangement. As the Supreme Court said in *Jefferson Parish*, 466 U.S. at 2:

> . . . the essential characteristic of an invalid tying arrangement lies in the seller's exploitation of its control over the tying product to force the buyer into the purchase of a tied product that the buyer either did not want at all, or might have preferred to purchase elsewhere on different terms. When such "forcing" is present, competition on the merits in the market for the tied item is restrained and the Sherman Act is violated.

These present facts are very similar to those in *American Mfrs.*, 388 F.2d 272. In that case, a television broadcaster priced its advertising spots so that it only was commercially reasonable for an entity to purchase advertising on many of the broadcaster's stations in a package. Plaintiff alleged that this arrangement constituted an illegal tying arrangement in violation of the antitrust laws because it "did not want to advertise over 32 of these stations [but only did so] . . . because [the defendant] refused to make available the 95 stations [the plaintiff]

did want – except at an unreasonable cost . . ." *Id.* at 276. In reversing the district court's grant of summary judgment, the Second Circuit held that such an economically coercive offer could constitute *per se* tying under Section 1:

> Where there is no quality or distinguishing desideratum between a product offered singly or in a package, the seller cannot charge substantially higher for the individual product if the price differential has the effect of conditioning the sale of the single product to the sale of the entire package and if the difference in price cannot be legitimately justified by cost considerations.

Id. at 283 (emphasis added).

The Amgen tying arrangement constitutes a blatant case of economic coercion. The price for Amgen's tying product, its WBCGF drugs, on a stand-alone basis, is "substantially higher" than under Amgen's pricing scheme. *See supra* pp. 11-12. As a result, oncology clinics have no economically viable option but to accept Amgen's bundle and to forego purchasing substantial amounts of Procrit.

c. Amgen Has Market Power in the Relevant Market.

A tying arrangement is *per se* unlawful where, as here, the defendant has "market power . . . to force a purchaser to do something that he would not do in a competitive market" – purchase the tied product from the seller of the tying product. *Jefferson Parish*, 466 U.S. at 14. As the Supreme Court noted in *Jefferson Parish*, market power is the supplier's power to induce his customer for one product to buy a second product from him that would not otherwise be purchased solely on the merit of that second product. *Id.* at 14 n.20 (*quoting* Areeda and D. Turner, Antitrust Law ¶ 1134 (1980).

Market share is often an indication of market power. *See Town Sound,* 959 F.2d at 479 ("the defendant's share of the [tying product] market is so high that it occupies a dominant market position.") (citing *Jefferson Parish*, 466 U.S. at 16-17). Amgen has market power in the

sale of the tying product – WBCGF drugs. Amgen has a 98% share of WBCGF drug sales to oncology clinics. *See supra* p. 6; *See Eastman Kodak,* 504 U.S. at 464 ("The existence of [market] power is inferred from the seller's possession of a predominant share of the market."). Moreover, the demand for WBCGF drugs is inelastic, as there are no substitutes for them. *See Brown Shoe v. United States*, 370 U.S. 294, 325 (1962) (setting forth market definition standards).

Another factor to consider is whether the barriers to entry in the WBCGF drug market are high. *See Allen-Myland, Inc. v. International Bus. Machs. Corp.*, 33 F.3d 194, 209 (3d Cir. 1994) ("Notwithstanding the extent of an antitrust defendant's market share, the ease or difficulty with which competitors enter the market is an important factor in determining whether the defendant has true market power."). No entity has entered the WBGCF drug market other than Berlex, and there are no entities on the horizon that are seeking approval from the Food and Drug Administration to supply a WBCGF drug. Amgen's formidable patent portfolio itself presents a significant barrier to entry into the WBCGF market. Moreover, the cost and time involved in the discovery, development and regulatory approval process to market a pharmaceutical biologic are staggering. *See* Yang Decl. ¶¶ 11, 14.

Finally, Amgen has the power to force a sizeable number of oncology clinics to meet its demands. The Supreme Court has made clear that the market power inquiry in a tying case concerns "whether the seller has the power to raise prices, or impose other burdensome terms such as a tie-in, with respect to any appreciable number of buyers within the market." *Fortner Enters., Inc. v. United States Steel Corp.*, 394 U.S. 495, 504 (1969). The fact that an appreciable number of Procrit purchasers – such as oncology clinics with a significant number of Medicare patients – are now economically coerced by Amgen's tying arrangements into

purchasing Aranesp clearly establishes that Amgen has market power in the market for the tying product.

d. Amgen's Tie Affects a Not Insubstantial Amount of Commerce

A not insubstantial amount of commerce is "in absolute dollar terms . . . an amount which is not de minimis in terms of the 'total volume of sales tied by the sales policy under challenge.'" *Allen-Myland*, 33 F.3d at 201 (quoting *Fortner Enters.*, 394 U.S. 495).

This element is satisfied here. Sales to oncology clinics of RBCGF drugs by Ortho and Amgen this year will exceed $2.8 billion. *See* Yang Decl. ¶9. These dollar sales and market shares shifts that will result from Amgen's unlawful conduct certainly effect a substantial amount of commerce -- far greater than the *de minimis* threshold required by the courts. *See Allen-Myland*, 33 F.3d at 216 ($20 million of sales in tied product enough to satisfy 'not insubstantial' amount of commerce element).

e. Harm to Competition is Presumed.

Where a tying arrangement is *per se* illegal, "the need for . . . inquiry into actual competitive conditions" is "obviate[d]." *Jefferson Parish*, 466 U.S. at 27. Indeed, the Supreme Court stated many times in its seminal *Jefferson Parish* decision that *per se* treatment disposed of a plaintiff's burden to prove that a tying arrangement caused anticompetitive effects. *See id.*, 466 U.S. at 9 (the unreasonableness of *per se* tying arrangements are presumed "without the necessity of any analysis of the market context"); *id.* at 15 ("Per se condemnation [is] condemnation without inquiry into actual market conditions . . ."; *id* at 26 ("per se rule against tying . . . avoid[s] analysis of actual market conditions"); and *id.* at 29 (only "in the absence of *per se* liability, . . . [can] inquiry into the actual effect . . . on competition" be made).

This well-established principle follows prior Supreme Court precedent. For example, in *Northern Pacific,* 356 U.S. at 5, the Court held that tying arrangements that violate Section 1 *per se* have a "pernicious effect on competition and lack [] any redeeming virtue." Thus, held the *Northern Pacific* Court, tying arrangements that satisfy *per se* criteria are "conclusively presumed to be unreasonable and therefore illegal without elaborate inquiry as to the precise harm they have caused or the business excuse for their use." *Id. See also International Salt Co. v. United States*, 332 U.S. 392, 396 (1947) (affirming summary judgment to plaintiff on tying claim and holding that it was not error for district judge to "preclude[] trial of alleged issues of fact as to whether the restraint was unreasonable within the Sherman Act.").

The Third Circuit has followed this precedent. *See Town Sound*, 959 F.2d at 477 (where *per se* analysis is utilized to adjudge tying claim "the plaintiff is . . . relieved of proving actual harm to competition and of rebutting justifications for the tie-in.").

In light of the foregoing, Ortho need not present any evidence of effects or illegitimacy of business justification in order to succeed on its *per se* tying claim.

* * *

Accordingly, Ortho is likely to succeed on its claim that Amgen's tying arrangement is a *per se* violation of Section 1.

2. <u>Ortho Will Likely Succeed On Its Attempt To Monopolize Claim</u>.

The Supreme Court has held that an attempt to monopolize in violation of Section 2 occurs where a defendant (1) has a specific intent to monopolize, (2) engages in exclusionary or anti-competitive conduct and (3) has a dangerous probability of monopolizing the relevant market. *Spectrum Sports, Inc. v. McQuillan,* 506 U.S. 447, 456 (1993). *See Callahan v. A.E.V., Inc* , 2000 U.S. Dist. LEXIS 7869, *9 (W.D. Pa. May 5, 2000) (citing *Barr Labs., Inc. v. Abbott Labs* , 978 F.2d 98, 112 (3d Cir. 1992) (summary judgment to defendant denied where number of

plaintiff competitors decreased during time that defendant engaged in alleged anticompetitive conduct)).

Here, Amgen's pricing schemes are a blatant attempt to monopolize the sale of RBCGF drugs to oncology clinics by use of its WBCGF monopoly.

a. Amgen Has Specific Intent To Monopolize RBCGF Markets.

Amgen's pricing schemes have the following goals – to extend Amgen's dominance in RBCGF drugs prescribed for chemotherapy patients in oncology clinics and to reinforce its WBCGF drug monopoly. To obtain continued access to Amgen's monopoly WBCGF drugs at economically viable prices, oncology clinics must purchase upwards of 65-90% of their RBCGF requirements from Amgen. *See supra* 11-12. As a result, clinics will have little or no inclination to carry Procrit.

These facts standing alone are sufficient to support an inference of intent to monopolize. *Spectrum Sports,* 506 U.S. at 892 (anticompetitive "conduct may be sufficient to prove the necessary intent to monopolize"); *Tops Mkts., Inc. v. Quality Mkts., Inc.*, 142 F.3d 90, 101 (2d Cir. 1998); *Yeager's Fuel, Inc. v. Pennsylvania Power & Light Co.*, 953 F. Supp. 617, 639 (E.D. Pa 1997) (citing *Pennsylvania Dental Ass'n v. Medical Serv. Ass'n of Pennsylvania*, 745 F.2d 248, 260 (3d Cir. 1984) denying defendants' motion for summary judgment on specific intent issue by, among other things, inferring such intent from predatory discounting).

Moreover, the use of Amgen's WBCGF drug monopoly to attempt to monopolize RBCGF drug markets has no legitimate, efficiency-enhancing rationale.[6] *See Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 604 (1985) (conduct is predatory when attempt to exclude has "some basis other then efficiency.") Amgen cannot show that it engaged in

[6] Any argument that Amgen is simply offering "discounts" is irrelevant to the question of whether the *tying of Aranesp to its dominant Neulasta/Neupogen drugs has a legitimate business purpose*. Amgen could, of course, offer discounts on Neupogen/Neulasta and Aranesp without tying these products together.

bundling the two pharmaceutical products at issue in order to "directly or indirectly. . . enhance[] consumer welfare." *LePage's Inc. v. 3M*, 324 F.3d 141, 163 (3d Cir. 2003), *cert. denied*, 124 S. Ct. 2932, 159 L.Ed.2d 835 (2004) (quoting *Data Gen. Corp. v. Grumman Sys. Support Corp.*, 36 F.3d 1147, 1183 (1st Cir. 1994)).

Amgen's pricing scheme accomplishes two things. First, the volume requirements on Aranesp will effectively foreclose patient access to Procrit in oncology clinics notwithstanding that many clinics prefer Procrit based on efficacy and stand-alone price, as reflected by Procrit's 55% market as of the first quarter of 2004. *See supra* p. 10. Second, the use of rebates on WBCGF products to require clinics to buy Aranesp will not result in a lower ASP on Aranesp. As a result, the government (and consumers) will pay higher reimbursements on Aranesp than otherwise required were Amgen forced to provide head to head discounts on Aranesp. *See supra* pp. 13-15.

The Court can infer a predatory intent from such conduct. *See e.g.*, *Aspen Skiing*, 472 U.S. at 610 (holding that discounting of multi-day lift ticket that applied to multiple ski slopes "supports an inference that the monopolist made a deliberate effort to discourage its customers from doing business with its smaller rival" who only could offer consumers access to one ski slope.)

Moreover, in this Circuit, even if Amgen could demonstrate that it was "[acting] in furtherance of its economic interests," *i.e.*, if there were some business rationale, this would not be sufficient in the face of evidence of Amgen's specific intent to monopolize. *LePage's Inc.*, 324 F.3d at 163-64 (finding no efficiency justification for offering rebates when bundling its dominant premium scotch tape products with private label scotch tape products).

Expedited discovery of Amgen will provide further evidence of the purpose behind its pricing schemes.

b. Amgen Has Engaged In Exclusionary Conduct.

Amgen's pricing scheme constitutes unlawful exclusionary conduct. In this Circuit, it is clear that offering "major customers substantial rebates to induce them to eliminate or reduce their purchases" from a competitor can be anti-competitive and unlawful exclusionary conduct, whether or not the defendants' rebates cause the products to be sold below cost. *LePage's*, 324 F.3d at 159.

The anticompetitive effects of Amgen's pricing scheme are substantial. Ortho, an entity that does not have a WBCGF drug, is Amgen's only competitor in the RBCGF drug market and it cannot match these discounts for the reasons described on pp. 15-18. Accordingly, unless enjoined, the resulting foreclosure of Ortho from RBCGF drug markets will mean less innovation, reduced choice and, ultimately, higher prices for consumers. *See LePage's*, 324 F.3d at 159 ("It has been recognized . . . that the foreclosure of one significant competitor from the market may lead to higher prices and reduced output.") (quotation omitted).

In *LePage's*, the Third Circuit affirmed a jury award that found a monopolist had engaged in illegal exclusionary conduct when it offered multi-product rebates on its dominant brand name products to entities that purchased substantial volumes of its private label products as well. The *LePage's* court held that "[t]he principal anticompetitive effect of bundled rebates . . . is that when offered by a monopolist they may foreclose portions of [a] market to a . . . competitor who does not manufacture an equally diverse group of products and who therefore cannot make a comparable offer." *Id.* at 155. *See also SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1065 (3d Cir. 1978) (Section 2 judgment for plaintiff affirmed where pharmaceutical monopolist "link[ed] products on which [it] faced competition . . . with a competitive product"

by offering a mere 3% volume rebate on dominant and competitive products when purchased as a bundle).

The conduct at issue here is quite similar, in essential respects, to that condemned previously by the Third Circuit in *LePage* and *SmithKline*. Amgen is providing substantial rebates on its dominant WBCGF products only if the purchaser buys two or more separate Amgen products, and only if the purchasing oncology clinic commits to purchase a predominant share of its RBCGF drugs from Amgen. Moreover, Ortho does not have a WBCGF drug. Hence, it does not have the ability to compete with its own bundle of WBCGF and RBCGF drugs. Amgen's pricing scheme effectively coerces oncology clinics to buy Aranesp, thereby rendering Procrit no longer a viable competitive product. *See supra* pp. 15-17. Such conduct is anticompetitive, exclusionary and illegal.

c. There is a Dangerous Probability That Amgen Will Monopolize the Relevant RBCGF Drug Markets.

(i) Oncology Clinics are a Relevant Market.

The test for establishing the confines of a relevant market is well established. A relevant market is defined by "the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *Brown Shoe*, 370 U.S. at 325 (1962); *SmithKline*, 575 F.2d at 1063. Moreover, where the contours of a market are well-recognized by industry participants, its economic coherence is demonstrated. *Brown Shoe* at 325 (market definition may be determined by "practical indicia [such] as industry or public recognition" of the market); *Ansell, Inc. v. Schmid Labs., Inc* , 757 F. Supp. 467, 471 (D.N.J. 1991), *aff'd without opinion*, 941 F.2d 1200 (3d Cir. 1991) (citing *General Food Corp. v. FTC*, 386 F.2d 936, 941 (3d Cir. 1967)).

Here, Ortho's experts will demonstrate that the sale and distribution of RBCGF drugs to oncology clinics (including so-called "mixed use" clinics) constitutes a relevant market as supported by the "practical indicia" set forth in *Brown Shoe*. Oncology clinics are a distinct industry segment of purchasers and dispensers of RBCGF drugs because they (1) use different vehicles to collectively bargain for drugs such as specialized group purchasing organizations; (2) pay different prices for RBCGF drugs;[7] (3) are reimbursed by government health care programs in amounts that differ from those received by other industry participants; (4) purchase drugs through distinct vehicles such as "specialty distributors"; and (5) are viewed by drug industry participants as a unique segment of the health care industry. *See supra* 6-7.

All of these factors weigh in favor of the recognition of a cognizable market for purposes of the antitrust laws. *See, e.g., Ansell,* 757 F. Supp. at 471-75 (sale of retail brand name condoms to retail distributors constitutes an "economically significant submarket" based on industry recognition, packaging distinctions for sale to retail outlets versus government, unique production facilities, and distinct customers and prices);[8] *F.T.C. v. Staples, Inc.*, 970 F. Supp. 1066, 1075-78 (D.D.C. 1997) (finding a relevant product submarket for office superstores (separate from a broader market for all office supply sellers) where, among other things, type of customers targeted and served differ from those of other sellers of office supplies).[9]

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[7] Courts have deemed that products are in separate markets when the price for one of the products is at least five percent higher than the prices of the other. *See, e.g., United States v. Archer-Daniels Co.*, 866 F.2d 242 (1988) (holding that corn syrup and sugar are in different markets when employing 5% test); *United States Dep't of Justice and Federal Trade Commission, Horizontal Merger Guidelines*, § 1.11 (1992), as revised (1997) (advocating that agencies use five percent test to analyze market definition)

[8] In *Ansell*, the court held that "[a]lthough dippers [condom manufacturers] may sell their products through a number of different channels of distribution, the evidence presented to the Court clearly shows that the industry participants view their sales to the retail trade as a separate economic entity." 757 F. Supp. at 472.

[9] The *Staples* court held that office superstores are in a separate market for the following reasons: "Superstores are different from many other sellers of office supplies due to the type of customer they target and attract. The superstores' customer base overwhelmingly consists of small businesses with fewer than 20 employees and consumers with home offices. In contrast, mail order customers are typically mid-sized companies with more than 20 employees. Another example is contract stationers who focus on serving customers with more than 100

(ii) Amgen Will Likely Dominate the Oncology Clinic Market for RBCGF Drugs

Amgen's share of sales to the largest group of customers of RBCGF drugs, oncology clinics, has grown substantially as a result of the pricing schemes it has rolled out over the past two years. In the first quarter of 2004, Amgen's Aranesp accounted for approximately 45% of the sales of RBCGF drugs to oncology clinics. Now, after two years of Amgen linking its dominant WBCGF drugs with Aranesp, Aranesp's share is approximately 65%. *See supra* p. 10. With its latest pricing scheme, Amgen seeks virtually to eliminate Procrit sales in the oncology clinic market.

Now, with an approximately 65% market share on its tied product and a share of 98% on its tying product, Amgen is likely to further enhance its dominant share of sales to oncology clinics. The latest pricing scheme provides incentives for Aranesp to have upwards of a 65% to 90% share of sales. And, with these types of volume requirements, few clinics will be willing to run the risk of utilizing any significant volume of Procrit for fear of jeopardizing rebates on Amgen's RBCGF and WBCGF drugs. *See supra* 10-15.

Amgen's present market share in the sale of RBCGF drugs to oncology clinics is more than sufficient to evidence a dangerous probability that a defendant will monopolize a relevant market via exclusionary means. *See Rebel Oil Co. v. Atlantic Richfield Co.*, 51 F.3d 1421, 1438 (9th Cir. 1995) (holding that "44 percent is sufficient as a matter of law to support a finding of market power" in an attempted monopolization case when coupled with evidence of high barriers to entry and competitive inability to expand output in response to supra-competitive pricing); *H.J., Inc. v. International Tel. & Tel. Corp.*, 867 F.2d 1531, 1543 (8th Cir. 1989)

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employees. While the Court accepts that some small businesses with fewer than 20 employees as well as home office customers do choose other sellers of office supplies, the superstores' customers are different from those of many of the purported competitors." 970 F. Supp. at 1078.

(dangerous probability of monopolization found where defendant has no market share); *Yeager's Fuel*, 953 F. Supp. at 648-49 (defendants' motion for summary judgment on attempted monopolization claim denied where it maintained a 31% share of relevant market and its share of submarket was even larger).

Consequently, Ortho can establish a dangerous probability that Amgen will succeed in its monopolization scheme unless enjoined.

B. Ortho Will Suffer Irreparable Harm.

The standard for a finding of irreparable injury in an antitrust case is somewhat more liberal than in the ordinary case. To establish irreparable harm under the antitrust laws, a plaintiff "need only demonstrate a *significant threat of injury* from an impending violation of the antitrust laws or from a contemporary violation likely to continue or recur." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 130 (1969) (emphasis added) (quoting 15 U.S.C. § 26); *see also ECRI v. McGraw-Hill, Inc.*, 809 F.2d 223, 225 (3d Cir. 1987); *Central Jersey Freightliner, Inc. v. Freightliner Corp.*, 987 F. Supp. 289, 296 (D.N.J. 1997) (requiring a "clear showing of immediate, irreparable injury or a presently existing threat"). The Supreme Court has encouraged a liberal construction of this requirement "not merely to provide private relief but to serve as well the high purpose of enforcing the antitrust laws." *Zenith Radio*, 395 U.S. at 130-131.

In this Circuit, irreparable harm generally consists of injury for which "monetary damages are difficult to ascertain or are inadequate." *Hohe v. Casey*, 868 F.2d 69, 73 (3d Cir. 1989); *Bascom Food Prods. Corp. v. Reese Finer Foods, Inc.*, 715 F. Supp. 616, 640 (D.N.J. 1989). However, in some cases "economic injury can be so severe as to warrant preliminary injunctive relief: the loss of business and good will, and the threatened loss of the enterprise itself, constitute irreparable injury to the plaintiff sufficient to justify the issuance of a preliminary injunction." *Beilowitz v. General Motors Corp.*, 233 F. Supp. 2d 631, 644 (D.N.J.

2002) (quotations omitted); *see also Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 596 (3d Cir. 2002); *Pappan Enters., Inc. v. Hardee's Food Sys., Inc.*, 143 F.3d 800, 805 (3d Cir. 1998).

Loss of goodwill gives rise to irreparable harm because it is so "difficult to quantify," *Yong Ki Hong v. KBS Am., Inc.*, No. 05-Civ. 1177, 2005 WL 1712236, *2 (E.D.N.Y. Jul. 22, 2005) and it is "not [ ] possible to measure plaintiffs actual loss of customers and goodwill that will necessarily occur." *C & A Carbone, Inc. v. Town of Clarkstown*, 770 F. Supp. 848, 854 (S.D.N.Y. 1991); *see also Bergen Drug Co. v. Parke, Davis & Co.*, 307 F.2d 725, 728 (3d Cir. 1962) ("It would be impossible to estimate or compute plaintiff's damages for the loss of good will which it will suffer as a result of being unable to provide its retail customers with service at least equally as good as [defendant's]"); *Tully v. Mott Supermarkets, Inc.*, 337 F. Supp. 834, 851 (D.N.J. 1972) (finding it "virtually impossible to put a collective dollar and cent valuation" on goodwill).

Loss of "goodwill" can occur through (1) declines in consumer trust or loyalty, (2) permanent loss of consumers or other business opportunities, (3) inability to continue supplying consumers, or (4) loss of a competitive advantage. *See, e.g., Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co.*, 22 F.3d 546, 552 (4th Cir. 1994) (possible permanent loss of customers to a competitor); *Highmark, Inc. v. UPMC Health Plan, Inc.*, 276 F.3d 160, 170-71 (3d Cir. 2001) (defendant's "gaining an unfair advantage in its competition"); *Bascom*, 715 F. Supp. at 637 (causing "customers and potential customers [to] turn" away from plaintiff); *Boyertown Burial Casket Co. v. Amedco, Inc.*, 407 F. Supp. 811, 817 (E.D. Pa. 1976) ("lack of customer confidence in [plaintiff's] future").

Amgen's unlawful conduct exposes Ortho to more than a mere "threatened" loss. Ortho cannot offer comparable rebates on its RBCGF drug to offset Amgen's actual and disguised rebates on Aranesp to oncology clinics. As a result, Ortho faces crippling losses in customer loyalty and good will as a result of its inability to supply its consumers with Procrit at a fair price in the marketplace. See *Reuters Ltd. v. United Press Int'l, Inc.*, 903 F.2d 904, 908 (2d Cir. 1990) (finding irreparable harm in loss of customers and revenue and the competitive disadvantage resulting from inability to supply customers); *Interphoto Corp. v. Minolta Corp.*, 417 F.2d 621, 622 (2d Cir. 1969) (per curiam); *Bergen Drug*, 307 F.2d at 728 (finding irreparable harm where defendant's conduct prevented plaintiff from offering pharmacies the full-line, full-service product they expected); *Yong Ki Hong*, 2005 WL 1712236 at *2 (finding irreparable harm where plaintiff could no longer offer certain products, causing customers to threaten "to stop patronizing plaintiffs" if the inability persisted).

Moreover, as a result of this "threatened loss of good will and customers, both present and potential," Ortho will become a much less desirable partner for other companies in terms of potential licensing, co-promotions and other research collaborations. *See supra* pp. 17-18; *Bascom*, 715 F. Supp. at 637; *cf. Premier Dental Prods. Co. v. Darby Dental Supply Co., Inc.*, 794 F.2d 850, 858 (3d Cir. 1986) (threat of losing exclusive distributorship contracts would constitute "irreparable harm"); *Allis-Chalmers Mfg. Co. v. White Consol. Indus., Inc.*, 414 F.2d 506, 516 (3d Cir. 1969) (finding irreparable harm where antitrust violations stalled plaintiff's proposed license agreement with a third party); *Alcatel Space, S.A. v. Loral Space & Communications Ltd.*, 154 F. Supp. 2d 570, 584 (S.D.N.Y. 2001) (finding that even while "the loss of [ ] contracts may not destroy [plaintiff's] business, the limited number of [contract] opportunities available warrants a finding of irreparable harm.").

This loss of goodwill and business threatens to substantially impact, if not eradicate, the flagship franchise in Ortho's product offering to oncology clinics. Such a "substantial loss of business accompanied by loss of good will" clearly constitutes irreparable harm. *Bristol Tech., Inc. v. Microsoft Corp.*, 42 F. Supp. 2d 153, 161 (D. Conn. 1998) (finding irreparable harm despite plaintiff's financial status since plaintiff faced a "substantial loss of business" to its "principle product and revenue generator"); *see also National Communications Ass'n, Inc. v. AT&T Co.*, 813 F. Supp. 259, 265 (S.D.N.Y. 1993) (eliminating service advantage that drew consumers to plaintiff posed a "threat to the very existence of [plaintiff's] business" and thus irreparable harm); *Sylvan Seal Milk, Inc. v. Milk Control Comm'n of the Commonwealth of Pennsylvania*, 264 F.Supp. 1001, 1004-05 (E.D. Pa. 1967) (finding irreparable harm where competitors' sales of large quantities of milk at cheap prices precluded plaintiff, which sold small amounts at regular prices, from obtaining new business). If Procrit sales continue to plummet, as expected, Ortho's ability to invest in research and development—the sustenance of a biotechnology company, as well as licensing opportunities —will be severely impaired. *See supra* pp. 17-18.

C. The Public Interest and a Balancing of the Equities Weigh in Ortho's Favor

The public interest will be served by entry of a preliminary injunction. *See Atlantic Coast Airlines Holdings, Inc. v. Mesa Air Group, Inc.*, 295 F. Supp. 2d 75, 96 (D.D.C. 2003); *Moor Corp. Ltd v. Wallace Computer Servs., Inc.*, 907 F. Supp. 1545, 1582 (D. Del. 1995). Procrit is a useful effective drug that has helped millions of cancer patients struggling with chemo-induced anemia. *See supra* pp. 17-18. Denying patient and physician choice by tying access to WBCGF drugs at an economically viable price to buying Aranesp instead of public does not serve the public well.

"The public interest is served by ensuring no unreasonable restraints on competition." *Atlantic Coast*, 295 F. Supp. 2d at 96. If not preliminarily enjoined, Amgen will continue its efforts to illegally dominate the RBCGF clinic market and beyond, causing irreparable harm to Ortho's RBCGF business and denying physicians and patients' choice on the RBCGF drug they wish to use.

Granting Ortho preliminary relief in no way prejudices Amgen. Amgen is free to aggressively market and price its RBCGF and WBCGF businesses. It simply cannot use the monopoly it has on one drug to dominate another drug market. *See FTC v. H.J. Heinz Co.*, 246 F.3d 708, 726 (D.C. Cir. 2001) ("The principle public equity weighing in favor of issuance of preliminary injunctive relief is the public interest in effective enforcement of the antitrust laws.").

* * *

Accordingly, a preliminary injunction should issue.

II. THIS COURT SHOULD PERMIT EXPEDITED DISCOVERY.

Expedited discovery is available under Rules 26(d), 30(a)(2) and 34(b) of the Federal Rules of Civil Procedure, and under Rule 26.1(b) of the Local Civil Rules of this Court. Under Local Rule 26.1, ordinary discovery procedures, including the timing and sequence thereof, may be modified or suspended in favor of expedited discovery where "good cause" is shown.

In this case, Ortho needs expedited discovery to further support its motion for a preliminary injunction. Courts routinely grant expedited discovery in cases like this one, where preliminary injunctive relief if sought. *See, e.g., TKR Cable Co., v. Cable City Corp.*; 267 F.3d 196, 198 (3d Cir. 2001); *Acierno v. Mitchell*, 6 F.3d 970, 973 (3d. Cir. 1993); *Glaxosmithkline Consumer Healthcare, L.P., v. Merix Pharm. Corp.*, No. Civ. 05-898, 2005 WL 2230318 (D.N.J.

Sept. 13, 2005) *Barre-National, Inc. v. Doshi*, No. Civ. 88-1847, 1988 WL 36335 (D.N.J. Apr. 18, 1988); *Capital City Publ'g Co. v. Trenton Times Corp.*, 575 F. Supp. 1339, 1342 (D.N.J. 1983) (all granting or approving of expedited discovery).

The discovery that Ortho seeks is set forth in the Exhibits to the Cavanaugh Declaration. Ortho has specifically tailored its discovery requests to information relevant to these proceedings. This limited expedited discovery is necessary to, among other things, uncover the full extent of Amgen's bundled pricing schemes to oncology clinics, the intent of these schemes and Amgen's understanding and perception of the relevant markets for RBCGF drugs and WBCGF drugs. *See* Cavanaugh Decl. ¶¶ 5-8.

The burden on Amgen to submitting to limited discovery on an expedited basis is slight when weighed against the harm to competition, and patient access and physician choice, that delaying judicial review of Amgen's tying arrangement will produce. The burden of compiling the information being requested is further limited by the fact that Ortho's request for injunctive relief involves recent events. *See id at* ¶ 9

Only expedited discovery will allow a fair adjudication of the merits of Ortho's motion for a preliminary injunction. *See id* at ¶ 8. Accordingly, the Court should direct the parties to proceed with expedited discovery and set a date for an evidentiary hearing on Ortho's motion seeking a preliminary injunction.

CONCLUSION

For the reasons set forth above, this Court should grant Ortho's motion for expedited discovery, and enter a preliminary injunction, enjoining Defendant Amgen from continuing to engage in its illegal conduct.

Dated: Trenton, New Jersey
October 11, 2005

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